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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/187,385 11/06/98 MARKOVIC

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HM12/1109

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EXAMINER

MARK S ELLINGER
FISH AND RICHARDSON
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HOLLERAN, A	
ART UNIT	PAPER NUMBER

1642

DATE MAILED:

11/09/01

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/187,385

Applicant(s)

MARKOVIC, SVETOMIR N.

Examiner

Anne Holleran

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-6, 8-12, 18, 21, 22 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-6, 8-12, 18, 21, 22 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☒ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The amendment filed August 2, 2001 is acknowledged. The indicated allowability of claim 26 is withdrawn in view of newly discovered prior art. The finality of the last Office action is withdrawn. Rejections on the newly cited art follow.

2. Claims 1-3, 7, 19, 20 and 23-25 were canceled.

Claims 4-6, 8-12, 18, 21, 22 and 26 are pending and examined on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. Claims 4-6, 8, 18, 21, 22, and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Tovey et al (U.S. Patent 5,997,858; issued Dec. 7, 1999; filed May 9, 1997); claims 9-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Tovey et al in light of Brittenden et al (Brittenden, J. et al. Cancer, 77(7): 1226-1243, 1996, April).

Claim 26 is drawn to a method for stimulating the immune system of a human patient having a non-resectable malignant tumor, comprising administering alpha-ineferon to said patient and treating said patient with non-surgical medical methodologies to diminish said tumor,

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wherein the dosage of alpha-interferon is about 500 U/m^2 to about $1,000,000 \text{ U/m}^2$ per day. Claims 4-6 recite alternate ranges of dosages (500 U/m^2 to $500,00 \text{ U/m}^2$, 500 U/m^2 to $250,000 \text{ U/m}^2$, and 500 U/m^2 to $1,000,000 \text{ U/m}^2$). Claim 8 limits claim 26 to a dosage that is administered once per day. Claims 18-22 limit the claimed methods to treatment of various cancers such as breast cancer, lung cancer, pancreatic cancer, brain cancer, prostate cancer, ovarian cancer, uterine cancer, renal cancer, and melanoma.

Tovey teaches methods of administering, oromucosally, alpha-interferon in comparable dosage ranges, 5000 U to about $20 \times 10^6 \text{ U}$, with a preferable range of $1 \times 10^4 \text{ U}$ to about $1 \times 10^6 \text{ U}$. The dosage ranges taught for alpha interferon in man (column 2, lines 25-38) and may be administered once per day (see claim 2). Tovey teaches treating renal cell carcinoma, malignant melanoma, lung cancer, and brain tumors (column 2, lines 4-16). Tovey teaches a method where the interferon is administered in combination with chemotherapy or radiation therapy (column 2, lines 54-57). In addition, Tovey teaches that the mechanism for the beneficial effects of alpha-interferon may be due to stimulation of lymphoid tissue surrounding the nasopharyngeal and oral cavities. Thus, it appears that Tovey teaches immunostimulatory dosages.

Claims 9 and 11 recite that the dosage increases NK lymphocyte cytotoxicity at least 50 percent or 75 percent above NK lymphocyte cytotoxicity measured prior to administering alpha-interferon. Claims 10 and 12 recite that the NK lymphocyte toxicity is measured at effector to target cell ratios of 15:1 to 50:1. Because Tovey teaches methods using dosages that are within the range of those recited in the instant claims, Tovey inherently teaches the methods of claims 9-12. Additionally, the ability of alpha-interferon to increase NK-lymphocyte activity is an inherent effect of the administration of alpha-interferon, as evidence by the teachings of

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Brittenden. Brittenden teaches alpha-interferon enhances NK cell activity and has been successfully used in the treatment of renal carcinoma as part of a therapeutic regimen comprising the administration of interleukin-2 (see page 1234, 2nd column).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

ALH

Anne L. Holleran
Patent Examiner
November 8, 2001

AC

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